UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,981	01/25/2001	Aladar A. Szalay	13070-1	5416

7590 08/07/2003

SHELDON & MAK
Attn: David A. Farah, M.D.
225 South Lake Avenue, Suite 900
Pasadena, CA 90101

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	9

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,981	SZALAY ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed April 14, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claims 13-22 have been cancelled. Claims 1-3 and 6-12 have been amended. Claims 1-12 are under consideration in this office action.

Drawings

2. The drawings are objected to because of the reasons set forth in the attached PTOL-948. However, the corrections will not be held in abeyance and applicant must submit proposed drawing corrections in response to the requirement in the Office action.

Withdrawal of Rejections

3. The written description rejection of claims 1-12 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicants' amendments and arguments.

The rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendments and arguments.

Response to Arguments

4. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of R j ction

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Loessner et al. The claims are drawn to a method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material comprising providing living bacteria with a first detectable signal; placing the modified bacteria on the first side of the material and detecting whether the first signal is present on the material. Dependant claims are drawn to the signal being in the visible spectrum and the bacteria incorporating functional luciferase.

Loessner et al., teach the evaluation of luciferase reporter bacteriophage for the detection of *Listeria* in contaminated foods. Loessner et al., also state that the need for rapid screening and detection of contamination in food items such as diary products, meats, vegetables and desserts is important (page 2961). Several procedures have been developed such as nucleic acid hybridization, nucleic acid amplification and antibody detection assays (page 2961). The authors have created a modified luciferase gene that was infected to the Listeria host (page 2961). Luciferase is a detectable signal. The aim was to create rapid and reliable detection of modified Listeria cells in several artificially contaminated samples (page 2961). Also enumeration procedures

were employed. The samples were artificially contaminated with the modified living bacteria at specific areas, thus these sites qualify as a first side. The samples were treated with enrichment cultures in order to be evaluated (page 2962). A luminometer was used to measure luminescence (page 2963). The number of bacteria cells was also determined, see table 3. Therefore, the luminometer can detect the bacteria wherever is the bacteria is located such as on the first and second sides of a material. The use of luciferase in a detection method is especially applicable for rapid and inexpensive detection and the elimination of contamination in food and environmental samples (page 2965).

Therefore Loessner et al., teach a method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material comprising providing living bacteria with a first detectable signal; placing the modified bacteria on the first side of the material and detecting whether the first signal is present on the material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al., (US Patent 5,736,351) in view of Contag et al.

The claims are drawn to a method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material comprising providing living bacteria with a first detectable signal; placing the modified bacteria on the first side of the material and detecting whether the first signal is present on the material. Dependant claims are drawn to the signal being in the visible spectrum and the bacteria incorporating functional luciferase.

Miller et al., teach a method for detecting the presence and determining the quantity of contaminants present on a wide variety of surfaces of meat or other foodstuffs, equipment, materials in medical situations using bioluminescence or chemiluminscence (col. 1 lines 10-26). Miller et al., teach chemiluminescent detection by iosluminols and other similar visually detectable compounds (col. 2 lines 10-14). Thus, Miller et al., disclose using multiple and different bioluminescent labels. Microbial contamination is the significant cause of morbidity and mortality, therefore the rapid and routine quantitative determination of bacteria particularly those present of the surfaces of materials is of vital importance (col. 1 lines 27-31). The method procedures teach general bacterial screens on hard surfaces, screens on carcasses, and chemiluminscent Salmonella assays (col. 11-13). The luciferin/luciferase chemiluminscent reactions employing luciferase or other luminols for total microbial determinations can be easily adapted to the taught methods (col. 5 lines 20-24). The luminescence was detected using a photometer (col. 5 lines 60-62). However, Miller

et al., does not teach using modified living bacteria with incorporated functional luciferase.

Contag et al., teach photonic detection of bacterial pathogens in living host (abstract). Strains of Salmonella were marked with bioluminescence with a plasmid conferring the expression of luciferase (abstract). Bacterial luciferase emits photons and appeared to be a suitable source of bioluminescence for localizing pathogens in living host (page 594). The mouse hosts were infected with the modified bacteria (page 594). The authors demonstrated that bioluminescent light is transmitted through the tissue of an animal infected with that pathogen, thus allowing localization of the bacteria to specific body sites, which qualify as different sides of a material (page 594). Figure 2 shows the distribution of bioluminescence throughout the peritoneal cavity of the mouse, thereby allowing detection of the bacteria wherever it is located. The signal indicated differing amount of the modified bacteria that passes through the material or system of the host (page 596). The experimental procedures teach making the bioluminescent Salmonella, imaging the bioluminescence and determining the number of bacterial colonies (page 601).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the methods taught by Miller et al., to detect bacterial contamination using living bacteria with incorporated functional luciferase which produce a detectable signal as taught by Contag et al. One would have a reasonable expectation of success because no more than routine skill would have been required to exchange the two step method for creating modified bacteria of Miller et al., in view of Contag et al., for the

more convenient modified bacteria used to detect bacterial contamination which is well known in the art to detect such. No more than routine skill would have been required to make the modified bacteria that was already known in the art to be able to detect the bacteria. Moreover, the bioluminescence method for evaluating whether a material is contaminated with bacteria is well known in the art and been found to be rapid, inexpensive and convenient as compared to other detection methods.

7. Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al., (US Patent 5,736,351) and Contag et al., and further in view of Holen (US Patent 5,814,331).

The claims are drawn to a method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material comprising providing living bacteria with a first detectable signal; placing the modified bacteria on the first side of the material and detecting whether the first signal is present on the material. Dependant claims are drawn to evaluating a tooth.
Miller et al., and Contag et al., have been discussed above, however neither teach evaluating teeth.

Holen teaches that the bacteria on the surfaces of teeth and dental restorations have been a primary cause of gingivitis and periodonitis (col. 1 lines 25-29). There are non-surgical treatments directed at reducing these infective formations however, they are not very successful without the elimination or suppression of the pathogenic bacteria (col. 1 lines 35-39). Antimicrobials have been used to inhibit binding of

periodontal bacteria (col. 2-3 lines 65-3). Therefore the need to evaluate material used with naturally extracted teeth for bacterial infection is well known. Treatment of the infected periodontal space or pocket of the tooth is performed to prevent bacterial infection (col. 4 lines 8-20). The inventors also teach microbial examination of the periodontitis defects in a class of patients (col. 5 lines 42-56).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the methods taught by Miller et al., and Contag et al., to detect bacterial contamination on teeth as taught by Holen. One would have a reasonable expectation of success because no more than routine skill would have been required to exchange the materials of Miller et al., and Contag et al., for a tooth, since the art teaches that bacterial contamination of teeth can cause periodontal diseases. No more than routine skill would have been required to exchange the material being tested because it was already known in the art to be able to detect the bacteria on tooth surfaces.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
July 30, 2003